

REMARKS

Status of the Claims

Claims 1-52 are pending. Claims 1-11, 18-31 and 36-52 are withdrawn from consideration. Claims 12-17 and 32-35 are rejected.

Claims 12, 16, 17, 32 and 34 are amended herein. No new matter is added herein.

Claim amendments

Claim 17 is amended to overcome the 35 U.S.C. §112, second paragraph rejection. The recitation of "means for detecting said label" is canceled from claim 17. Hence, amended claim 17 recites a kit that may further comprise a label with which to label the probe recited in claim 16.

Claim 32 is amended to overcome the 35 U.S.C. §112, first paragraph (written description) requirement. Amended claim 32 limits the TADG-15 detected in the claimed method to TADG-15 DNA of SEQ ID NO: 1 or TADG-15 mRNA transcribed from the TADG-15 DNA. This amendment is supported by Examples 2, 3, 6, 10 and 11 of the instant invention. Additionally, claim 34 is amended to properly depend from amended claim 32.

Additionally, claim 12 is amended to recite that the probe used in the method is specific for TADG-15 mRNA transcribed from SEQ ID NO: 1. Similarly, claim 16 drawn to a kit for detecting TADG-15 mRNA is amended to recite an

oligonucleotide probe that is specific for TADG-15 mRNA transcribed from SEQ ID NO: 1.

The 35 U.S.C. §112, First Paragraph Rejection

Claims 32-35 stand rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

The Examiner states that although claim 32 and claims 12-17 may share essential subject matter such as method of detecting TADG-12 in a sample, claims 12-17 clearly express TADG-15 mRNA is detected using a probe specific for TADG-15 encoded by SEQ ID NO: 1, which is not the case with claims 32-35. Since there is no disclosure beyond the mention of SEQ ID NO: 1 as a TADG-15 nucleic acid in the instant specification, the Examiner states that claims 32-35 encompass variants, mutants and proteins from not only humans but other animals. Hence, the Examiner has maintained the rejection of claims 32-35.

Claim 32 is amended as described supra. Based on this amendment, the TADG-15 that is detected in such a method may be a TADG-15 DNA of SEQ ID NO: 1 or TADG-15 mRNA transcribed from this DNA. The instant specification is drawn to a TADG-15 that has a nucleic acid sequence of SEQ ID NO: 1. The instant specification discloses strategy that was used to identify this TADG-15. For instance, a RT-PCR was used to identify proteases overexpressed in human cancer (Example 10). Additionally, Northern blot was

used to examine size of the transcript for TADG-15 and its pattern of expression. Furthermore, a quantitative PCR was also performed to evaluate mRNA transcript expression in ovarian tumors and normal ovary (Example 11). Thus, by limiting the TADG-15 detected in the claimed method to a DNA with sequence of SEQ ID NO: 1 or an mRNA transcribed from this sequence, the amended claim 32 is thoroughly supported by the teachings of the instant invention and complies with the written description requirement. Accordingly, Applicant respectfully requests the withdrawal of rejection of claims 32-35 under 35 U.S.C. §112, first paragraph.

The 35 U.S.C. §112, Second Paragraph Rejection

Claim 17 stands rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Applicants respectfully traverse this rejection.

The Examiner states that when a claimed invention is defined using means plus a functional language, it is incumbent on the Examiner to correlate each claim limitation to all portions of the disclosure that describe the claim limitation. In the instant case, the Examiner states that the claim neither provides limitations that define the means nor correlates the detection of the label with any endpoint. Additionally, the Examiner states that there is no function language in regards to means for detecting the label. Since the means is not defined by the claims, the scope of the claims is not limited. Furthermore, the Examiner states that the means for detecting said label is not commensurate with the endpoint of the

method comprised in the kit. Hence, the Examiner has maintained rejection of the claim.

Claim 17 is amended as described supra and no longer recites means for detecting the label. Accordingly, based on the above-mentioned claim amendment and remarks, Applicants respectfully request the withdrawal of rejection of claim 17 under 35 U.S.C. §112, second paragraph.

Double Patenting Rejection

Claims 12-17 and 32-35 remain rejected under the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 5,972,616 (issued October 26, 1999). Applicants respectfully traverse this rejection.

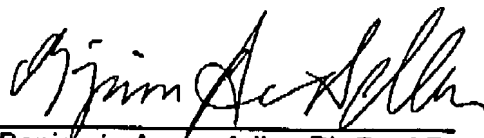
The Examiner states that claims of the instant application and claim 11 of the patent clearly share the same active steps and endpoint of detecting mRNA bound by a probe with hybridization. Based on this, the Examiner concludes that Applicants' assertion that the patent's claim reads on detection of the entire TADG-15 protein is not precise. Since the active steps are the same, the Examiner has maintained this rejection.

Applicants enclose a Terminal Disclaimer along with this response to obviate the obviousness-type double patenting rejection of claims 12-17 and 32-35 over claim 11 of U.S. Patent No. 5,972,616. Accordingly, based on this, Applicants respectfully request the withdrawal of double patenting rejection of claims 12-17 and 32-35.

This is intended to be a complete response to the Final Office Action mailed February 20, 2007. A Terminal Disclaimer and Form PTO-2038 is also enclosed with this response. Applicant submits that the pending claims are in condition for allowance. If any issues remain outstanding, please telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

Date: April 24, 2007


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**TERMINAL DISCLAIMER TO OBIATE A DOUBLE PATENTING
REJECTION OVER A "PRIOR" PATENT**Docket Number (Optional)
D8064CIP/D2

In re Application of: O'Brien et al.

Application No.: 10/600,187

Filed: June 20, 2003

For: TADG-15; An Extracellular Serine Protease Overexpressed in Breast and Ovarian Carcinoma

The owner, The Bd of Trustees of the Univ. of Ark System, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term prior patent No. 5,972,616 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:

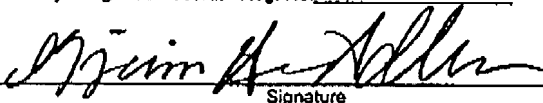
- expires for failure to pay a maintenance fee;
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- is found invalid by a court of competent jurisdiction;
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- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

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2. ☒ The undersigned is an attorney or agent of record. Reg. No. 35,423


Signature

4/24/07
Date

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Typed or printed name

(713) 270-5391
Telephone Number

- ☒ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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